

**REMARKS**

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and the reasons that follow.

**I. Status of the Claims**

Claims 1-39 are pending in this application, and claims 1-16, 19, 24, 25, 27-32, 36 and 37 are withdrawn. Upon entry of this amendment, new claim 40 will be added.

Claim 17 is amended and recites “an interface configured to contact the porous surface” and “a solvent removal element configured to absorb solvent from the administration reservoir by evaporation when the interface is in contact with the porous surface.” Exemplary support for this claim language can be found in paragraphs [0035] and [0037] and [0059] and FIG. 1 of the Application as filed.

Claim 33 is amended and recites “ wherein the control device is interconnected with at least one sensor for measuring a condition of the at least one active substance within the administration reservoir.” Exemplary support for this claim language can be found in paragraph [0068] and FIG. 3.

Claim 26 is amended to more clearly state the invention. No new matter has been added with the amendments.

New claim 40 is added. Exemplary support for this claim language can be found in paragraph [0066] of the Application as filed.

Applicants believe that each of the rejections raised by the Examiner have been addressed and the application is in condition for allowance. Reconsideration and allowance of the application, as amended, is respectfully requested. It is acknowledged that the foregoing amendments are submitted after final rejection of the claims. However, because the amendments

do not introduce new matter, and either place the application in condition for allowance or at least in better condition for appeal, entry thereof by the Examiner is respectfully requested.

## **II. Claim Rejections – 35 U.S.C. § 102**

Claims 17-18, 20-23, 26, 35, 38 and 39 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 6,374,136 to Murdock (“Murdock”). Office Action at pages 2-3. Applicants respectfully traverse this ground for rejection.

### **A. Independent Claim 17**

Applicants have amended claim 17 to further distinguish the claimed invention from the electrode assembly and the method of forming an anhydrous reservoir layer of the electrode assembly disclosed by Murdock.

Claim 17, as amended, recites “a solvent removal element configured to absorb solvent from the administration reservoir by evaporation *when the interface is in contact with the porous surface.*” Murdock does not disclose or teach a solvent removal element as recited in claim 17.

Murdock discloses an “electrotransport delivery device 10” that includes a “reservoir layer 24” that “contains the beneficial agent to be iontophoretically delivered.” *See* col. 6, lines 14-15 and lines 31-33. Murdock discloses solvent removal as a step in the formation of the reservoir layer, and, as noted by the Examiner, Murdock discloses that the “solvent may be removed from the polymer membrane by drying the membrane in a forced air oven, a vacuum drying oven, a desiccator, or by lyophilizing the polymer membrane.” *See* col. 5, lines 48-51, and Office Action page 3. Thus, solvent removal, as taught by Murdock, is a step in the manufacture of an electrode assembly, and does not occur when the device is in use (i.e., solvent removal as taught by Murdock does not occur when the device is in contact with a user’s skin). In contrast to Murdock, claim 17, as amended, recites a solvent removal element that that is configured to absorb solvent *when the interface is in contact with the porous surface.*

Further, to anticipate a claim the “identical invention must be shown in *as complete detail as is contained in the ... claim.*” MPEP § 2131 quoting *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir.1989) (emphasis added). Claim 17 recites a solvent removal element as one component of a device for transdermal administration of an active substance. As noted above, Murdock discloses removal of a solvent during the manufacture of the “reservoir layer” of “delivery device 10” by the use of drying devices such as ovens and desiccators. However, the drying devices (e.g., the ovens, desiccators, etc.) disclosed by Murdock are not a component of “delivery device 10” taught by Murdock. Thus, Murdock does not disclose a solvent removal element as one component of a device for transdermal administration of an active substance as recited in claim 17.

Because Murdock fails to disclose the device of amended claim 17, Applicants respectfully request withdrawal of the rejection of claims 17-18, 20-23, 26, 35, 38 and 39 under 35 U.S.C. § 102(b) based upon Murdock.

**B. Dependent Claims 38 and 39**

In addition to the reasons set forth above regarding independent claim 17, Applicants respectfully assert that dependent claims 38 and 39 are further patentable for the reasons set forth below.

Claim 38 recites “wherein *the solvent removal element controls the transfer of the active substance from the administration reservoir to the porous surface* by controlling the concentration of the at least one active substance in the administration reservoir.” Claim 39 recites “wherein *the solvent removal element controls termination of the transfer of the active substance from the administration reservoir to the porous surface* by drying the interface.” As discussed above, Murdock discloses solvent removal during manufacture of the reservoir layer and not during use of “delivery device 10.” As such, solvent removal as disclosed by Murdock is not related to the control of drug delivery by “delivery device 10.”

Accordingly, because Murdock fails to disclose the device of claims 38 and 39, Applicants respectfully assert that claims 38 and 39 are not anticipated by Murdock under 35 U.S.C. § 102(b).

### **III. Claim Rejections – 35 U.S.C. § 103**

Claims 33 and 34 were rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Murdock in view of U.S. Patent No. 5,993,435 to Haak et al. (“Haak”). Office Action at pages 3-5. Applicants respectfully traverse this ground for rejection.

Claims 33 and 34 depend from independent claim 17. For the reasons discussed above, Murdock fails to teach or suggest “a solvent removal element configured to absorb solvent from the administration reservoir by evaporation when the interface is in contact with the porous surface,” as recited in independent claim 17. Haak does not remedy the deficiencies of Murdock. Specifically, Haak discloses an “iontophoretic delivery device 10” that includes a “donor electrode assembly 8” having “a donor electrode 11, an electrolyte reservoir 13, a selectively permeable separator membrane 14 and an agent reservoir 15” and a “counter electrode assembly 9.” See col. 6, lines 52-54 and col. 7, lines 1-3. However, Haak does not teach or suggest “a solvent removal element configured to absorb solvent from the administration reservoir by evaporation when the interface is in contact with the porous surface,” as recited in independent claim 17.

Dependent claims 33 and 34 are patentable over Murdock in view of Haak for at least the following additional reasons. Claim 33, as amended, recites “at least one sensor for measuring a condition of the at least one active substance *within the administration reservoir*.” Haak does not teach or suggest such a sensor. Rather, Haak states generally that “[c]ontrol circuit 19 may also include an integrated circuit which could be designed ... to respond to sensor signals in order to regulate the dosage to maintain a predetermined dosage regimen.” Col. 11, lines 3-7. As an example of the signal that the control circuit is responsive to, Haak discusses monitoring

“a biosignal” such as blood sugar level. See col. 11, lines 11-15. As such, Haak does not teach or suggest “at least one sensor for measuring a condition of the at least one active substance within the administration reservoir,” as recited in claim 33.

Accordingly, claims 33 and 34 are patentable over Murdock in view of Haak under 35 U.S.C. § 103(a). Withdrawal of this ground for rejection is respectfully requested.

#### **IV. New Claim 40**

New dependent claim 40 recites the “device of claim 17, further comprising a housing, wherein the administration reservoir, the dispensing device, and the solvent removal element are located within the housing.” As noted above, the drying devices (e.g., the ovens, desiccators, etc.) disclosed by Murdock are not a component of “delivery device 10” taught by Murdock and are not located within a housing along with any other components of “delivery device 10.”

Accordingly, because Murdock fails to disclose the device of claim 40, Applicants respectfully assert that claim 40 is not anticipated by Murdock under 35 U.S.C. § 102(b).

#### **V. Conclusion**

Applicants believe that the present application is in condition for allowance. Favorable reconsideration of the application, as amended, is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

It should be noted that, for the sake of clarity and simplicity, Applicants’ remarks have focused on the rejections of the independent claims and certain dependent claims set forth in the Office Action with the understanding that the dependent claims are patentable for at least the same reasons as the independent claims. Further, in addressing the Examiner’s rejections, Applicants’ remarks have set forth only some of the available arguments for patentability of the rejected claims. Applicants expressly reserve the right to argue the patentability of all claims

separately and to provide new, different, and/or additional arguments for patentability not set forth herein, including, but not limited to, the failure of cited references to disclose, teach, or suggest other elements of the claims, the lack of motivation to combine cited references, or teaching away from the combination of cited references, in this or any future proceedings.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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